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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,984	02/18/2004	Evgenia Mandrusov	05618.P2926D	5727

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BLAKELY SOKOLOFF TAYLOR & ZAFMAN
1279 OAKMEAD PARKWAY
SUNNYVALE, CA 94085-4040

EXAMINER	
LEACH, CRYSTAL I	
ART UNIT	PAPER NUMBER
3737	
MAIL DATE	DELIVERY MODE
04/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,984	MANDRUSOV ET AL.	
	Examiner	Art Unit	
	CRYSTAL I. LEACH	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2004* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/12/2004;10/06/2004;2/18/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The Information Disclosure Statements (IDS) submitted on February 18, 2004, October 6, 2004 and October 12, 2004 are in compliance with 37 CFR 1.97 and 1.98. The references therein have been considered.

Drawings

2. Figures 1-11 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 2 is objected to because of the following informalities: The semicolon on line 5 of claim 2 needs to be replaced with a period. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Vigil et al. (6,102,904).

6. Regarding claim 1, Vigil et al. teach a method comprising positioning a delivery device at a location in a blood vessel; advancing the delivery device a distance into a wall of the blood vessel to a treatment site beyond an external elastic lamina of the blood vessel; and after advancing the delivery device, introducing a treatment agent through the delivery device (see abstract and fig. 2-16C).

7. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kaplan et al. (5,941,868).

8. Regarding claim 1, Kaplan et al. teach method comprising positioning a delivery device at a location in a blood vessel; advancing the delivery device a distance into a wall of the blood vessel to a treatment site beyond an external elastic lamina of the blood vessel; and after advancing the delivery device, introducing a treatment agent through the delivery device (see abstract and col. 2, l. 18 – col. 3, l. 58).

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Hofling (5,354,279).

10. Regarding claim 1, Hofling teaches method comprising positioning a delivery device at a location in a blood vessel; advancing the delivery device a distance into a wall of the blood vessel to a treatment site beyond an external elastic lamina of the blood vessel; and after advancing the delivery device, introducing a treatment agent through the delivery device (see abstract and fig. 1, 2, 5, 8, 11, 10 and col. 1, l. 48 – col. 3, l. 51).

11. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Faxon et al. (5,464,395).

12. Regarding claim 1, Faxon et al. teach method comprising positioning a delivery device at a location in a blood vessel; advancing the delivery device a distance into a wall of the blood vessel to a treatment site beyond an external elastic lamina of the blood vessel; and after advancing the delivery device, introducing a treatment agent through the delivery device (see abstract and fig. 1, 3, and 8-19 and col. 2, l. 42 - col. 3, l. 61).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 2,3,4, 5,6, 7, 8,9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil et al. or Kaplan et al. or Hofling or Faxon et al. in view of Hiki et al. (5,499,630).

The embodiments of the apparatus taught Vigil et al., Kaplan et al., Hofling and Faxon et al. do not teach imaging a portion of a wall of the blood vessel. However, imaging probes and catheters are well known in the art. It would have been obvious to one of ordinary skill in the art at the time of the invention to include image capabilities in any of these catheters in order to improve visualization and instrument guidance to a desired region of interest within a vessel or to a treatment area. It would be obvious to

one of ordinary skill in the art that any of these devices would be capable of treating per-adventitial space or its surrounding regions. Specifically, Kaplan et al. teach that therapeutic agents may be delivered to neointimal, intimal, medial, adventitial and perivascular spaces (see col. 2, l. 6-61). The catheter systems taught by Vigil et al. or Kaplan et al. or Hofling or Faxon et al. are capable of being maneuvered to a location as desired by a user for a particular treatment. Kaplan et al. teach that the treatment agent is capable of sustained release and is therefore, in a sustained release carrier (see col. 3, l. 42-58). It would be obvious to one of ordinary skill in the art utilize a variety of treatment agents having various average diameters in order to treat a particular region of interest.

Hiki et al. teach a catheter type ultrasound probe capable of performing ultrasound imaging and optical imaging of a region requiring treatment (see fig. 1-5 and col. 4, l. 38-60). It would be obvious to one of ordinary skill in the art that ultrasonic imaging capabilities will enable imaging of a thickness of a portion of the blood vessel wall.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include imaging in the inventions of Vigil et al. or Kaplan et al. or Hofling or Faxon et al., in light of the teachings of Hiki et al., in order to enhance the utility of the delivery catheter.

15. Claims 10- 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan et al. in view of Roorda et al. (5,540,912) or Slepian et al. (5,575,815).

Kaplan et al. teach delivery of therapeutic agents for promotion of angiogenesis (see abstract) wherein the agents comprise fibroblast growth factor, vascular endothelial growth factor, fibrinolytic agents and polymer agents (see col. 3, l. 42-58 and col. 4, l. 25-64). It would be obvious to one of ordinary skill in the art that an agent capable of promoting angiogenesis is also capable of being an opsonin-inhibitor and inducing an inflammatory response. There exists a finite number of therapeutic agents and it would therefore be obvious to a skilled person in the arts to substitute or try any number of the agents in order to achieve the desired or anticipated result of stimulating angiogenesis.

Roorda et al. teach a multitude of controlled-release therapeutic agents that could be substituted to achieve the goal of stimulating angiogenesis (see col. 3, l. 50 - col. 9, l. 6).

Slepian et al. also teach a number of therapeutic agents that could be substituted into the invention of Kaplan et al. (see col. 5, l. 1- col. 6, l. 50; col. 7, l. 10 – col. 11, l. 26).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include any number of therapeutic agents in the invention of Kaplan et al., in light of the teaching of Roorda et al. or Slepian et al., in order to obtain desirable results of angiogenesis stimulation.

16. Claims 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofling (5,354,279) in view of Hiki et al. (5,499,630).

Hofling teaches an apparatus comprising a catheter, a dilatable balloon, and at least one needle (see col. 1, l. 48 – col. 3, l. 51).

Hofling does not teach that the catheter has imaging capabilities.

Hiki et al. teach a catheter type ultrasound probe capable of performing ultrasound imaging and optical imaging of a region requiring treatment (see fig. 1-5 and col. 4, l. 38-60). It would be obvious to one of ordinary skill in the art that ultrasonic imaging capabilities will enable imaging of a thickness of a portion of the blood vessel wall.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include imaging in the inventions of Vigil et al. or Kaplan et al. or Hofling or Faxon et al., in light of the teachings of Hiki et al., in order to enhance the utility of the delivery catheter.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Crowley (5,588,432) teaches catheters for imaging, sensing electrical potentials, and ablating tissue; Hamm et al. (5,546,948) teach an ultrasound imaging guidewire; and Altman et al. (6,086,582) teach a cardiac drug delivery system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRYSTAL I. LEACH whose telephone number is (571)272-5211. The examiner can normally be reached on Monday through Friday, 8 am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/
Supervisory Patent Examiner, Art Unit 3737

CIL
/Crystal I Leach/
Examiner, Art Unit 3737